

**REMARKS**

Claims 1-33 and 35-70 are currently pending. New claim 70 has been added herein. Support for this new claim can be found in originally filed claims 1 and 5, and further, in the instant specification at paragraph [0062]. No new matter has been added by these amendments.

**1. Rejections under 35 U.S.C. §103(a) over Vega, et al.**

Reconsideration is requested of the rejection of claims 1-8, 10, 12-23, 25-33, 35-40, 42, 44-56, and 58-61, and 62-69 under 35 U.S.C. §103(a) as being unpatentable over Vega, et al. (U.S. Patent No. 6,153,209).

Claim 1 is directed to an absorbent product comprising an absorbent substrate and a moisturizing and lubricating composition. The moisturizing and lubricating composition comprises from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) an immobilizing agent, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. The immobilizing agent is a high molecular weight polyethylene glycol having the formula:  $\text{H}(\text{OCH}_2\text{CH}_2)_x\text{OH}$ ,

wherein x is the degree of ethoxylation and is an average value of at least about 20 moles.

Vega, et al. is directed to absorbent articles having a skin care composition deposited on at least a portion of the article. The skin care composition is a breathable, barrier protectant which can be immobilized on the article and is transferable to the wearer's skin via contact, normal wearer motion, and/or body heat. The skin care composition may comprise an emollient in an amount of from about 5 to about 95 wt.% of the skin care composition; an immobilizing agent in an amount of from about 5 to about 95 wt.% of the skin care composition, and optionally a humectant. Vega, et al. state that the compositions preferably fully melt at a temperature significantly above room temperature, and typically are applied to the article by heating the composition to a temperature in the range from about 35°C to about 150°C prior to application. Vega, et al. also state that the compositions preferably have a melt profile wherein 2-50% of the composition is liquid at room temperature (20°C).

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103. "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated

reasoning with some rational underpinning to support the legal conclusion of obviousness."<sup>1</sup> The Court in KSR International further identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art reference that would have led one of ordinary skill to modify the prior art reference to arrive at the claimed invention. Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as the cited reference fails to show each and every limitation of Applicants' invention and there is no apparent reason for one skilled in the art to modify the reference to arrive at each and every limitation. It simply

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<sup>1</sup> In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Applicants respectfully submit that Vega, et al. fail to disclose a composition comprising the specific combination of an immobilizing agent that is a high molecular weight polyethylene glycol having the formula:  $H(OCH_2CH_2)_xOH$ , wherein x is the degree of ethoxylation and is an average value of at least about 20 moles, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent. Nor is there any motivation in Vega, et al. to arrive at such a composition.

For instance, Applicants maintain that Vega, et al. fail to disclose a composition comprising from about **1% (by weight) to about 40% (by weight) of a compatibilizing agent** at all. The Office has cited column 26, line 5 of Vega, et al. as disclosing compatibilizing agents. As the Office has correctly noted, Vega, et al. do disclose that their compositions may comprise propylene glycol, butylene glycol, and certain low molecular weight polyethylene glycols (e.g., PEG-2, PEG-3, etc.),<sup>2</sup> which may be considered compatibilizing agents.<sup>3</sup> Vega, et al., however, fail to teach or suggest the amounts of these agents that may be present in the compositions described therein, and in particular, fail to teach or suggest compositions comprising from about 1% (by weight) to about 40% (by weight) of these compounds or of compatibilizing agents generally.

In Response to Applicant's arguments, citing In re Aller<sup>4</sup>, the Office has stated that although Vega, et al. fail to mention

<sup>2</sup> See Vega, et al. at col. 26, lines 5-7, and col. 27, lines 48-49.

<sup>3</sup> See specification at p. 25, ¶67.

<sup>4</sup> 220 F.2d. 454, 456; 105 USPQ 233, 235 (CCPA 1955).

the amounts of components such as propylene glycol, butylene glycol, and certain low molecular weight polyethylene glycols, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Specifically, "wherein the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

While Applicants agree that Vega, et al. teach optional components such as propylene glycol, butylene glycol, and certain low molecular weight polyethylene glycols, Vega, et al. fail to recognize these components as compatibilizing agents, and further, **fail to even recognize the need for any compatibilizing agents.** As noted in the specification of the present invention, the compatibility of the moisturizing and lubricating compositions of the present invention is important for the processability and stability of the compositions. In particular, paragraph 66 of the specification states:

Incompatible compositions require a more rigorous process to ensure that mixing is complete so as to prevent the separation of the different components in the composition. More mixing requires higher energy consumption, which leads to an increase in the cost of manufacturing the products. Further, it may be very difficult for an incompatible composition to maintain acceptable stability during the life of the product, starting with shipping, transportation, and storage prior to ultimate use by the consumer. Many incompatible ingredients may tend to slowly separate from the surface of the product to which they are applied resulting in a loss of the properties of the

overall composition and a potential loss in the intended benefits.

The specification further states that certain components of the moisturizing and lubricating compositions, such as several of the immobilizing agents (e.g., high molecular weight polyethylene glycols), are incompatible with some humectants, such as glycerin.<sup>5</sup> Thus, in order to ensure a high degree of compatibility, the moisturizing and lubricating compositions include from about 1% (by weight) to about 40% (by weight) compatibilizing agent. Compatibilizing agents are thus important for improving processing of the compositions, and to ensure good compatibility and a substantially homogenous composition.

While Applicants recognize that in *In re Aller*, the court generally states that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation," Applicants assert that the Office must first consider that the particular parameter **was recognized** as a result-effective variable before the determination of the optimum or workable ranges of the parameter might be characterized as routine experimentation; that is, *Vega, et al.* must recognize the need for a compatibilizing agent in their composition prior to determining the optimum or workable ranges of compatibilizing agent. MPEP §2144.05(II)(B), citing *In re Antonie*, 195 USPQ 6 (CCPA 1977). None of the above-mentioned benefits of compatibilizing agents are disclosed or even recognized by *Vega*,

et al. In particular, Vega, et al. merely list propylene glycol, butylene glycol, and certain polyethylene glycols as suitable humectants for use in their compositions.<sup>6</sup> Alternately, Vega, et al. state that propylene glycol and polyethylene glycols are suitable solvents for preservatives that may be included in the compositions.<sup>7</sup> There is, however, no disclosure of using propylene glycol, butylene glycol, or low molecular weight polyethylene glycols as compatibilizing agents, or of the need for compatibilizing agents generally. Nor do Vega, et al. disclose suitable amounts of propylene glycol, butylene glycol, or low molecular weight polyethylene glycols for inclusion in their compositions. Consequently, why would one skilled in the art be motivated to determine the suitable amount of compatibilizing agent for including in the compositions of Vega, et al. when Vega, et al. fail to disclose or suggest the need for such agents, and the only disclosed uses for propylene glycol, butylene glycol, and polyethylene glycols are as humectants and/or solvents for preservatives? While one skilled in the art may be able to optimize the amount of humectant to incorporate into the compositions of Vega, et al. based on the disclosure therein, one skilled in the art would not and could not be motivated to determine a suitable amount of compatibilizing agent for inclusion in the compositions of Vega,

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<sup>5</sup> See Specification at p. 25, ¶67.

<sup>6</sup> See Vega, et al. at col. 26, lines 3-7.

<sup>7</sup> See Vega, et al. at col. 27, lines 48-49.

et al. given the lack of teaching or recognition of the benefits of doing so.<sup>8</sup>

Moreover, the Examiner cites MPEP §2144 on page 9 of the instant office action and states that "the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant." Applicants recognize, as is stated in the MPEP, that the prior art reference does not need to suggest the specific combination to achieve the same advantage for a determination of obviousness, however, applicants again note that there must be some apparent reason for one skilled in the art to modify (i.e., optimize the ranges in the instant case) the cited reference. The required reasoning is completely lacking in this situation. More specifically, while Applicants do not disagree in that Vega, et al. teach polypropylene glycols, butylene glycol, and certain polyethylene glycols, at best one skilled in the art, reading the Vega, et al. reference, could solely find motivation to optimize the range of these specific components when used as humectants in the composition of Vega, et al.; that is, one simply would not and could not be

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<sup>8</sup> In the Response to Arguments section, the Office has stated that any benefits of compatibilizing agents are inherent features of the agents. Applicants note that the lack of disclosure in Vega, et al. of the benefits of compatibilizing agents is relevant to the foreseeability of modifying the amounts of propylene glycol, butylene glycol, or low molecular weight polyethylene glycol that could optionally be included in the Vega, et al. compositions. As pointed out in the above passage, one skilled in the art would not be motivated to optimize the amounts of propylene glycol, butylene glycol, or low molecular weight polyethylene glycols that are suitable for compatibilizing, as that use is not disclosed in Vega, et al.



motivated to modify the ranges of these specific components for an entirely different use, such as for a compatibilizing agent.

Furthermore, Applicants' claim 1 requires the immobilizing agent to be a **high molecular weight polyethylene glycol having the formula  $H(OCH_2CH_2)_xOH$ , wherein x is the degree of ethoxylation and is an average value of at least about 20 moles.**

The Office has cited to column 26, lines 6-7 of Vega, et al. as disclosing applicants' claimed immobilizing agents. However, the PEGs listed in this passage are disclosed as being useful humectants and are **not** all high molecular weight PEGs that. In particular, Vega, et al. disclose PEG-2, PEG-3, PEG-30, and PEG-50. Specifically, PEG-2 and PEG-3 are clearly **not** high molecular weight polyethylene glycol having the formula:  $H(OCH_2CH_2)_xOH$ , wherein x is the degree of ethoxylation and is an average value of at least about 20 moles, as required by claim 1.

Specifically, at paragraph [0063] of Applicants' specification, the immobilizing agents will reduce the tendency of the emollient and humectant of the composition to migrate or flow by keeping the emollient and humectant primarily localized on the bodyfacing surface of the absorbent product. Furthermore, the immobilizing agent may provide a slight tackiness to the moisturizing and lubricating composition, which may further improve transfer of the composition to the skin or membrane of the wearer. To allow for these functions, it is preferable to use **high molecular weight** polyethylene glycols such as required in claim 1 as these compounds are solids at room temperature. As well known, the melting point of

polyethylene glycol increases as the molecular weight of the compound increases. For example, the melting points of various polyethylene glycols are given as follows: diethylene glycol (PEG-2) = -10-6°C (14-43°F); triethylene glycol (PEG-3) = -7°C (19°F); PEG 400 = 4-8°C (39-46°F); PEG 600 = 20-25°C (68-77°F); PEG 1500 = 44-48°C (111-118°F); PEG 4000 = 54-58°C (129-136°F); and PEG 6000 = 56-63°C (133-145°F).<sup>9</sup> As such, lower molecular weight polyethylene glycols (such as PEG-2 and PEG-3 taught in Vega, et al.) have melting points ranging below room temperature, and thus, cannot be solids at room temperature such as is desired of the immobilizing agent of the claimed invention.

Moreover, as Vega, et al. fail to make a distinction between the polyethylene glycols taught as suitable humectants; that is, there is no teaching that their higher molecular weight polyethylene glycols are more preferred or provide any advantage to the composition as compared to using their lower molecular weight polyethylene glycols. Accordingly, there is no teaching to one skilled in the art to select the higher molecular weight polyethylene glycols (e.g., PEG-30 and PEG-50) for the humectant in Vega, et al. over the lower molecular weight polyethylene glycol (e.g., PEG-2 and PEG-3). As there is no teaching that the components must be high molecular weight polyethylene glycols, and further, suitable polyethylene glycols taught in Vega, et al. include lower weight molecular polyethylene glycols such as PEG-2 and PEG-3, which are liquid at room temperature

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<sup>9</sup> See The Merck Index, 12<sup>th</sup> Edition, Merck & Co. Inc. and Sigma-Aldrich Handbook of Fine Chemicals, 2007-2008 at page 2023.

and can provide a soft, lubricious type feel (which is desirable of a humectant for use in the composition of Vega, et al.), there is no teaching that these components **necessarily function effectively as the immobilizing agents** as required in Applicants' claim 1. As such, while Vega, et al. may teach various polyethylene glycols, there is no reason for one skilled in the art to pick and choose between the polyethylene glycols for use as an optional humectant in the composition of Vega, et al., and specifically, to choose PEG-30 or PEG-50 over PEG-2 and PEG-3 as the humecant.

Additionally, the Office has stated that high molecular weight PEGs are disclosed in U.S. Patent No. 4,556,560 (citing column 13, lines 6-11), and that this patent is incorporated into Vega, et al. by reference on column 26, line 64, and as such, the teaching of using high molecular weight PEGs in an absorbent product should be treated as part of the Vega, et al. reference. The '560 patent referred to by the Office discloses methods for the treatment and prevention of diaper rash and diaper dermatitis using the topical application of a lipase-inhibiting agent, e.g., a water-soluble metallic salt, applied in combination with a barrier-like vehicle. The ointment compositions described in the '560 patent may comprise a mixture of short and long chain polyethylene glycols. In particular, column 13, lines 7-11 states that the high molecular weight polyethylene glycol polymers "have an average molecular weight of about 2,000 or greater, preferably about 3,000 or greater, and, more preferably about 4,000 to about 6,000."

Applicants respectfully note that the '560 patent is cited by Vega, et al. as describing a non-limiting example of skin care agents that may be used in the compositions of Vega, et al. As noted above, the "skin care agent" in the '560 patent is the lipase-inhibiting agent, **not** the high molecular weight polyethylene glycols. Nowhere do Vega, et al. state that the high molecular weight polyethylene glycols disclosed in the '560 patent should or could be used in their compositions as an immobilizing agent. It is thus clear that Vega, et al. are teaching that the skin care agents of the '560 patent may be incorporated into their compositions. There is, however, no recognition or suggestion that high molecular weight PEGs should or could be used as immobilizing agents in the compositions of Vega, et al.

Furthermore, the '560 patent is only one of a large group of patents and applications cited by Vega, et al. as disclosing suitable skin care agents. More particularly, the '560 patent is merely one patent in a list of at least thirteen different patents and applications that Vega, et al. state disclose suitable skin care agents. Applicants respectfully submit that this is not a teaching by Vega, et al. to use high molecular weight polyethylene glycols as immobilizing agents in the compositions of Vega, et al.

Additionally, applicants note that in order to arrive at applicants' claim 1, one skilled in the art must pick and choose from a myriad of options in the Vega, et al. reference, without any guidance as to which options to choose to arrive at applicants' claim 1. At a minimum, one skilled in the art must

choose, without the benefit of applicants' disclosure as a blueprint, two optional embodiments from Vega, et al. and combine these optional embodiments into a single embodiment.

Specifically one skilled in the art would have had to first decide to include propylene glycol, butylene glycol, or certain low molecular weight polyethylene glycols into the composition, all of which are listed in Vega, et al. as optional components in the compositions of Vega, et al.; specifically as suitable humectants or in the case of propylene glycol and polyethylene glycols, also as solvents for preservatives. After deciding to include one or more of these optional components, one skilled in the art would then have to determine the amount of propylene glycol, butylene glycol, or certain low molecular weight polyethylene glycols to include into the composition. However, as noted above, Vega, et al. do not disclose that any of these agents may be used as compatibilizing agents, or disclose the need for compatibilizing agents in general. Thus, the optimization of amounts for these agents must be done with no guidance by Vega, et al. as to what should be optimized.

One skilled in the art would then have to decide to select an immobilizing agent from a laundry list of thirteen patents and applications listed by Vega, et al. as disclosing optional skin care agents, with no guidance provided by Vega, et al. that suitable immobilizing agents are listed in any of those patents or applications, and then select the '560 patent from this list, again with no guidance by Vega, et al. to select this particular patent from the laundry list of thirteen patents and applications. One skilled in the art must then incorporate a

high molecular weight polyethylene glycol as disclosed in the '560 patent into the composition as an immobilizing agent. Again, all this must be done with **no guidance** by Vega, et al. as to the benefits of a composition comprising the specific combination of from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent and an immobilizing agent that is a high molecular weight polyethylene glycol having the formula:  $\text{H}(\text{OCH}_2\text{CH}_2)_x\text{OH}$ , wherein  $x$  is the degree of ethoxylation and is an average value of at least about 20 moles. Applicants respectfully submit that it is simply not obvious to make such a combination based on the lack of guidance provided by the disclosure of Vega, et al.

With all due respect, it appears that the Office has used impermissible hindsight analysis and reconstruction when modifying the cited reference. What is important is that there is no guidance provided by Vega, et al. to arrive at the specific combination of from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent and an immobilizing agent that is a high molecular weight polyethylene glycol having the formula:  $\text{H}(\text{OCH}_2\text{CH}_2)_x\text{OH}$ , wherein  $x$  is the degree of ethoxylation and is an average value of at least about 20 moles in a composition.

In light of the foregoing, Applicants respectfully submit that claim 1 is patentable over Vega, et al.

Claims 2-8, 10, 12-23 and 25-31 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

Independent claim 32 is directed to an absorbent product comprising an absorbent substrate and a moisturizing and lubricating composition comprising from about 1% (by weight) to about 40% (by weight) of a silicone, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) an immobilizing agent, from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent and a dispersing agent wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C, and wherein the immobilizing agent is a high molecular weight polyethylene glycol having the formula:  $H(OCH_2CH_2)_xOH$ , wherein x is the degree of ethoxylation and is an average value of at least about 20 moles.

Claim 32 is patentable for the same reasons as set forth above for claim 1. In particular, Vega, et al. fail to disclose or provide any guidance as to a composition comprising the specific combination of from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent and an immobilizing agent that is a high molecular weight polyethylene glycol having the formula:  $H(OCH_2CH_2)_xOH$ , wherein x is the degree of ethoxylation and is an average value of at least about 20 moles in a composition.

Claims 33, 35-40, 42, 44-56, and 58-61 depend directly or indirectly from claim 32 and are therefore patentable for the

same reasons as set forth above for claim 32 as well as for the additional elements they require.

Claim 62 is similar to claim 1 and further requires the immobilizing agent to be a high molecular weight polyethylene glycol selected from the group consisting of PEG 3350, PEG 6000, PEG 8000, and PEG 10,000. Claim 62 is patentable over the combination of cited references for the same reasons as claim 1, as well as for the additional limitations it requires.

Specifically, no where in either of the references is a polyethylene glycol selected from the group required in claim 62 taught or suggested. At best, Vega, et al. suggest using PEG 30 and PEG-50 as suitable humectants. No where, however, are higher molecular weight polyethylene glycols **even mentioned**. Furthermore, as noted above, there is no teaching of a desire for using any polyethylene glycol as an immobilizing agent, and particularly, any higher molecular weight polyethylene glycol, as an immobilizing agent for reducing the tendency of the emollient and humectant of the composition to migrate or flow by keeping the emollient and humectant primarily localized on the bodyfacing surface of the absorbent product. Accordingly, claim 62 is patentable over the cited references. Furthermore, claims 63-69, which depend from claim 62, are patentable over the cited references for the same reasons as claim 62, as well as for the additional limitations they require.



**2. Rejections under 35 U.S.C. § 103(a) over Vega, et al. and Bowser, et al.**

Reconsideration is requested of the rejection of claims 1, 24, 32, and 57 as being unpatentable over Vega, et al. (U.S. Patent No. 6,153,209) in view of Bowser, et al. (U.S. Patent No. 5,342,976).

Claim 1 and Vega, et al. are discussed above.

Bowser, et al. disclose a composition suitable for topical application to human skin. The composition comprises an active ingredient that can control skin barrier functions; particularly, the active ingredient can moisturize and treat skin surfaces that have become excessively dry, fissured, eroded, or otherwise damaged. Specifically, the active ingredient is (a) a long chain  $\omega$ -hydroxy fatty acid or a carboxy-substituted derivative, (b) an hydroxy- or epoxy-derivative of an essential fatty acid, or an ester formed between (a) and (b). The composition further comprises a vehicle to enable the active ingredient to be conveyed to the skin in an appropriate dilution. One suitable vehicle is water. In one embodiment, the compositions can be used in a liquid-impregnated fabric, such as a tissue wipe.

Claim 1 is patentable over Vega, et al. for the reasons set forth above. In particular, Vega, et al. fail to disclose a composition comprising the specific combination of an immobilizing agent that is a high molecular weight polyethylene glycol having the formula:  $\text{H}(\text{OCH}_2\text{CH}_2)_x\text{OH}$ , wherein x is the degree of ethoxylation and is an average value of at least about 20 moles, and from about 1% (by weight) to about 40% (by weight) of

a compatibilizing agent. Bowser, et al. fail to overcome these deficiencies. In particular, Bowser, et al. fail to disclose a high molecular weight polyethylene glycol, as set forth in claim 1. The combination of Bowser, et al. and Vega, et al. thus fails to disclose or suggest all the limitations of claim 1.

Furthermore, as noted above, in establishing obviousness, the Office must show references that teach all of the claimed limitations along with some reason, either in the references themselves or in knowledge generally available to one skilled in the art, to modify and/or combine the references and arrive at the claimed subject matter. The mere fact that the references can be modified and combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. In *re Mill*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). A close reading of the cited references clearly indicates that one skilled in the art would not have been so motivated and, without Applicants' disclosure as a blueprint (which the Office had the benefit of utilizing), such a combination of the compositions of the Vega, et al. and the Bowser, et al. references would not have been made.<sup>10</sup>

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<sup>10</sup> M.P.E.P. §2142 further provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, as stated by the Federal Circuit, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. *Grain Processing Corp. v. American-Maize-Products, Co.*, 840 F.2d 902, 904 (Fed. Cir. 1988).

Applicants assert that there is nothing in the cited references or in the general knowledge of one ordinarily skilled in the art that would lead one skilled in the art to combine the Vega, et al. and Bowser, et al. references to arrive at Applicants' claim 1. Specifically, a close reading of the Bowser, et al. reference actually teaches away from the combination of the Vega, et al. and Bowser, et al. references.

Specifically, as noted above, it is desirable for the compositions of Vega, et al. to have a melt profile such that 2-50%, and preferably 3-25% of the components are liquid at room temperature (20°C).<sup>11</sup> Furthermore, Vega, et al. state that it is desirable for the emollient component of the compositions used therein to be substantially **anhydrous**. Vega, et al. define "substantially anhydrous" to mean the emollients or mixtures thereof typically have a water content of less than about 10%, preferably less than about 5%, more preferably less than about 1%, and most preferably less than about 0.5% by weight of the emollient component. It should be noted that as the emollients are only one component of the composition in Vega, et al., specifically, making up 5-95% by weight of the composition, the amount of water by weight of composition is even less. For example, even if the maximum of less than about 10% water was used with the emollient in the composition, water would be present in the composition as a whole in an amount of less than about 0.5 to 9.5%.

Vega, et al. further state that the substantially anhydrous character of the emollients avoids overhydration of skin and the

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<sup>11</sup> See Vega, et al. at col. 15, lines 14-15.

wicking effect of the absorbent core, which may draw emollient components toward the core, interfering with absorbency, and keeping the emollient away from the topsheet surface and the wearer's skin.<sup>12</sup>

In contrast, the Bowser, et al. composition can comprise from about 15% to 99.9999% by weight water and, preferably from 50% to 99.5% by weight water. As such, there is no apparent reason why one skilled in the art would combine the components of the Bowser, et al. reference, which are desirably incorporated into compositions having large amounts of water, e.g., at least 15% by weight water and, more preferably at least 50% by weight water, with the compositions of Vega, et al., which desirably limit the amount of components (such as water) that are liquid at room temperature, e.g., preferably comprise less than 50%, and more preferably 3-25% components that are liquid at room temperature. This is particularly true in view of Vega's concerns that the presence of water in the emollient component of the compositions may result in overhydration of the skin and may affect absorbency of the article. As such, there is no motivation or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1.

Moreover, the Examiner cites *Titanium Metals Corp. of America v. Banner* on pages 13-14 of the instant office action, regarding the amount of water disclosed in the Vega and Bowser references, stating that "a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not

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<sup>12</sup> See Vega, et al. at col. 18, lines 35-50.

overlap but are close enough that one skilled in the art would have expected them to have the same properties." Accordingly, the Examiner asserts that because Vega, et al. disclose a water content of 10% in the emollient and Bowser, et al. disclose a water content as low as 15%, that the ranges are "close enough" for one skilled in the art to combine the references. Applicants respectfully disagree.

Initially, as noted above, it should be recognized that the maximum water is less than about 10% **by weight of the emollient**, and thus, water would be present by weight of the composition in even less amounts. Furthermore, the case the Examiner cites is further explained in MPEP §2144.05, which states:

Court held as proper a rejection of a claim directed to an alloy of "having .08% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.

Applicants submit that the ranges determined to be "close enough" in that case differed by, at most, 0.05%. In the instant case, however, the Examiner asserts that a reference that discloses at most 10% water (which, is incorrect as noted above) and a reference that discloses at least 15% water are "close enough" to make a determination that one skilled in the art would not be discouraged from combining the references. Applicants submit that the difference in the disclosed ranges in the instant case is much larger than that of the case cited by the Examiner. Specifically, one skilled in the art would need to be motivated to increase the maximum amount of water disclosed in the Vega, et al. reference by at least 50% in order

to arrive at the minimum amount of water disclosed in the Bowser, et al. reference. One skilled in the art simply would not and could not be so motivated especially in light of Vega, et al.'s disclosure that the emollient component of their composition is "substantially anhydrous."

Furthermore, applicants acknowledge that column 25, lines 53-56 of Vega, et al. disclose that the compositions can comprise other components, such as water, however, nowhere does Vega, et al. give any indication of a suitable amount of water that may be added such that the emollient component of the composition remains substantially anhydrous, and the overall composition retains its desired results. As such, claim 1 is patentable over the cited references.

Claim 24 depends from claim 1 and is thus patentable over the cited references for the same reasons as set forth above for claim 1 as well as for the additional elements it requires.

Independent claim 32 and claim 57, which depends therefrom, are patentable over the cited references for the same reasons as set forth above for claim 1, as well as for the additional elements they require.

#### New Claim 70

New claim 70 is similar to claim 1 and further requires the humectant to be selected from the group consisting of N-Acetyl ethanolamine, urocanic acid, aloe vera gel, arginine PCA, chitosan PCA, copper PCA, corn glycerides, dimethyl imidazolidinone, fructose, glucamine, glucose, glucose glutamate, glucuronic acid, glutamic acid, glycereth-7,

glycereth-12, glycereth-20, glycereth-26, honey, hydrogenated honey, hydrogenated starch hydrolysates, hydrolyzed corn starch, lactamide MEA, lactic acid, lactose lysine PCA, mannitol, methyl gluceth-10, methyl gluceth-20, PCA, PEG-2 lactamide, PEG-10 propylene glycol, polyamino sugar condensate, potassium PCA, propylene glycol citrate, polyamino acid, polysaccharide, saccharide hydrolysate, saccharide isomerase, sodium aspartate, sodium lactate, sodium PCA, sorbitol, TEA-lactate, TEA-PCA, Urea, Xylitol, and mixtures thereof. Claim 70 is patentable over the combination of cited references for the same reasons as claim 1, as well as for the additional limitations it requires.

Specifically, no where in either of the references is a humectant selected from the group required in claim 70 taught or suggested. At best, Vega, et al. suggest that a humectant may optionally be used in their composition and suggest using PEG 30 and PEG-50 as suitable humectants if a humectant is indeed used in the composition. No where, however, are the specific humectants required in claim 70 **even mentioned**. Furthermore, as noted above, in order to arrive at applicants' claim 70, one must first choose to even utilize a humectant in their composition and then select one of the specific humectants of claim 70, which as noted above, are no where disclosed in the Vega, et al. and/or Bowser, et al. reference. According, claim 70 is patentable over the cited references.

### **3. Double Patenting Rejections**

Claims 1-8, 10, 12-33, 35-40, 42, and 44-61 have been provisionally rejected under the judicially-created doctrine of

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obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/659,862.

Applicants note this rejection is in fact a provisional obviousness-type double patenting rejection since U.S. Patent Application No. 10/659,862 has not yet issued as a patent. Applicants will address the merits of these rejections, as appropriate, if the listed application issues as a patent before the application at hand.



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**CONCLUSION**

In light of the foregoing, applicants request withdrawal of the rejections of claims 1-8, 10, 12-33, 35-40, 42, and 44-69 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required during the entire pendency of this application to Deposit Account No. 01-2384.

Respectfully Submitted,

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